REMARKS

Claims 4-9, 11-16, 18-32 and 34-48 remain in the present application.

Claim 44 has been amended to correct a typographical error.

Claim 19 has been amended to make it commensurate in scope with claim 34 (antecedent basis at claim 34).

Claim 33 has been canceled since it was not in appropriate U.S. claim format. In light of this, it is respectfully submitted that the rejection of that claim under 35 U.S.C. § 101 and § 112 is no longer applicable and it is respectfully requested that it be withdrawn.

The Examiner has rejected claims 4-9, 11-16 and 18-48, under 35 U.S.C. § 103(a), based on WO 98/03267 (Coffee), in view of U.S. Patent 4,197,289 (Sturzenegger et al.) and U.S. Patent 5,320,855 (Roche et al.). The Examiner contends that Coffee teaches electrohydrodynamic processes and apparatuses to form fibers, fibrils, webs and mats, and Sturzenegger et al. teaches making pharmaceutical dosage forms by depositing an active material onto a web and cutting the web into individual dosages. The Examiner then contends that it would have been obvious to use Coffee's disclosed electrohydrodynamic process to make the webs described in Sturzenegger et al. The Roche et al. patent is disclosed merely to teach the use of saccharine and peppermint flavorings in pharmaceutical dosage forms. For the reasons given below, this rejection is respectfully traversed.

Before considering this rejection in detail, the present invention will be briefly summarized. The present invention relates to an efficient and effective method for manufacturing a dissolvable tablet, e.g., a pharmaceutical tablet. In this method, a dissolvable carrier material is placed into an electric field so as to cause the formation of fibers or fibrils of the carrier. These fibers/fibrils then deposit on a support surface to form a mat or web. An active ingredient, such as a pharmaceutically active material, is incorporated into the mat or web as part of the formation process, and the mat or web is then formed into tablets. Preferred dissolvable carriers for use in this process include biodissolvable carriers, such as gelatin, starch, cellulose, cellulose derivatives, water-soluble polymers, polyvinyl pyrrolidone, polyvinyl alcohol, polysucrose, and sugar. The apparatus for carrying out this process is also claimed. The active ingredient may

either be coated onto the fibers and woven into the mat itself or may be contained within the core of the fibers. Either way, the active material is an integral part of the mat.

The Coffee application, cited by the Examiner, teaches electrohydrodynamic (EHD) spray techniques to form solid or gel particles, as well as fibers or fibrils. These materials are taught to be of particular use for deposition onto the skin. The application, at page 17, teaches the particular adaptability of these fibers/materials for use in a wound dressing in that they cover the wound, are lightweight, and allow air circulation around the wound. The fibers may contain a core or a coating of a biologically active material which may be delivered topically at the site of the wound. The biologically active material is incorporated integrally into the web or mat formed. The Coffee application does not teach or suggest the formation of tablets from the web or mat formed. The Coffee application does include an incidental disclosure of the oral administration of particles formed by the EHD process. However, Coffee does not teach an aspect of the present invention, i.e., the production of tablets from a mat formed from EHD fibers or fibrils.

To attempt to remedy this deficiency, the Examiner has cited the Sturzenegger et al. patent. The Sturzenegger et al. patent describes a method for forming solid dosage forms from a web. The web is formed using standard techniques from the paper- or film-forming industries. There is absolutely no suggestion to form the web using EHD or any other electrostatic spray technique. Once the web is formed, Sturzenegger et al. teach that the active material is then deposited onto the surface of the already-formed web; an electrostatic powder spray is disclosed as one way this can be done. The web is then cut and formed into dosage forms. As indicated, there is no suggestion to form the web in Sturzenegger et al. using EHD or any electrostatic spray technique. This raises two important points. First, the webs/products produced by Coffee and Sturzenegger are different: the active material is coated onto an already-formed web in Sturzenegger, while in Coffee the active material is actually integral to the web itself (incorporated either in or on the individual fibers). Thus, there would have been no reason for Sturzenegger et al. to use EHD since it would form a different product than that described in Sturzenegger et al. Secondly, EHD was a well-known web-forming technique at the time

Sturzenegger developed his product. For Sturzenegger et al. not to have used or disclosed EHD for making their web suggests that they realized that it would form a different product from the one they sought. Accordingly, one skilled in the art, on reading Sturzenegger et al., would have no reason to utilize the EHD spray technique taught in Coffee to make the webs and the tablets described in the Sturzenegger et al. patent.

It should also be pointed out that while Coffee et al. teaches forming webs and mats, it is not for the purpose of forming tablets, but rather for the purpose of forming dressings or coverings on wounds. A wound dressing needs to cover the wound, allow good air circulation, and allow for the egress of wound fluids. Unlike a pill, a wound dressing cannot dissolve or disintegrate quickly on tact with water and still be an effective wound dressing. While Coffee et al. teaches that the wound dressing may be bioresorbable, that is for the purpose of allowing a pharmaceutical active contained in the defined fibers to diffuse into the wound; the dressing itself cannot dissolve quickly and still be effective. Therefore, one reading Coffee et al. would have had no reason to consider tablets as described in Sturzenegger et al.

The Roche et al. patent does nothing to supplement the deficiencies of either the Coffee or the Sturzenegger et al. references. Roche et al. merely teaches the use of flavorants, such as saccharine or peppermint, in oral pharmaceutical dosage forms. The fact that saccharine or peppermint or other flavorants is known for use in pharmaceutical dosage forms is in no way disputed by the applicants herein. The Roche et al. patent does nothing to suggest the use of EHD or any other electrostatic spray technique to form a mat which is then formed into oral dosage tablets.

In light of the foregoing, it is respectfully submitted that the rejection under 35 U.S.C. § 103(a) is not applicable to the claims currently pending in the present application. Accordingly, it is respectfully requested that the rejection be withdrawn.

In light of the foregoing, reconsideration and allowance of the claims currently pending in the present application are earnestly solicited.

CERTIFICATE OF MAILING

I hereby certify that a copy of this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 this 25 day of November, 2003.

Sarah Ohlweiler

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Respectfully submitted,

Ronald Alan Coffee et al.

by _____
Steven J. Goldstein
Registration No. 28,079

FROST BROWN TODD LLC
2200 PNC Center
201 East Fifth Street
Cincinnati, Ohio 45202-4182
Telephone (513) 651-6131